REMARKS

Claims 154-172 and 241-249 were pending. Claims 154 and 245-246 have been amended. Support for the amendments of claim 154 can be found, for example, in paragraphs [0019], [0058] and [0080] of the present application as published (2004/0219214). Claims 245-246 have been amended to correct typographical errors. Claims 250-253 are new. Support for the new claims can be found, for example, in paragraph [0071], [0110] and Figure 6. No new matter is being introduced. Upon entry of these amendments, claims 154-172 and 241-253 will be pending.

Claim Rejections Under 35 U.S.C. §102

Claims 154-157, 161, 165-166, 168, 172 and 241-246 are rejected as being anticipated by U.S. Published Application No. 2001/0055615 to Wallace (hereafter "Wallace").

Wallace does not anticipate claim 154, as amended. Amended claim 154 is directed to a method of affecting biological processes *in vivo* comprising selecting an in vivo biological tissue comprising functional groups X; providing a composition comprising a synthetic polymer and a drug, the synthetic polymer comprising multiple activated groups Y, where Y is reactive with X; and forming covalent bonds between the synthetic polymer and the tissue by contacting the tissue with the composition of under conditions where i) X reacts with Y and ii) biological processes in the vicinity of the tissue are affected by the drug. Wallace does not disclose forming covalent bonds between a synthetic polymer having multiple activated groups and tissue in which the multiple activated groups (Y) of the synthetic polymer react with functional groups X of the tissue and wherein the synthetic polymer is not in admixture with any other polymer that is reactive with the synthetic polymer. Instead, Wallace discloses two synthetic polymers forming hydrogels by reacting with each other, the hydrogel being adhesive or cohesive to a tissue site. Accordingly, Wallace does not anticipate amended claim 154 or its dependent claims.

Claims 154, 155, 161, 169-172 and 241-246 are rejected as being anticipated by U.S. Patent No. 6,166,130 to Rhee (hereafter "Rhee").

Rhee does not anticipate claim 154, as amended. Rhee does not disclose forming covalent bonds between a synthetic polymer having multiple activated groups and tissue in which the multiple activated groups (Y) of the synthetic polymer react with functional groups X of the tissue and wherein the synthetic polymer is not in admixture with any other polymer that is reactive with the synthetic polymer. Instead, Rhee describes methods of using a crosslinked polymer gel formed by reacting two synthetic polymers containing, respectively, multiple electrophilic groups and multiple nucleophilic groups. Accordingly, Rhee does not anticipate amended claim 154 or its dependent claims.

Claims 154-157, 159 and 160 are rejected as being anticipated by U.S. Patent No. 5,631,011 to Wadstrom (hereafter "Wadstrom").

Wadstrom does not anticipate claim 154, as amended. Wadstrom does not disclose forming covalent bonds between a synthetic polymer having multiple activated groups and tissue in which the multiple activated groups (Y) of the synthetic polymer react with functional groups X of the tissue. Instead, Wadstrom describes methods of using a combination of fibrin and biodegradable polymer as tissue adhesive. The biodegradable polymer serves as a viscosity enhancer and does not have multiple activated groups that can react with functional groups of the tissue. Wadstrom's biodegradable polymers include, for example, polyglycans or polysaccharides, neither of which can form covalent bonds with the tissue. Accordingly, Wadstrom does not anticipate amended claim 154 or its dependent claims.

Claims 154, 155 and 158 are rejected as being anticipated by U.S. Patent No. 6,280,727 to Prior (hereafter "Prior").

Prior does not anticipate claim 154, as amended. Prior does not disclose forming covalent bonds between a synthetic polymer having multiple activated groups and tissue in which the multiple activated groups (Y) of the synthetic polymer react with functional groups X of the tissue. Instead, Prior describes methods of using a composition including stabilized thrombin and microfibrillar collagen. Prior discloses using hydrophilic polymers such as PEG as a thrombin stabilizer; however, there is no teaching or suggestion that the hydrophilic polymers contain multiple activated groups that can form covalent bonds

with functional groups of tissue. Accordingly, Prior does not anticipate amended claim 154 or its dependent claims.

Claim rejections under 35 U.S.C. §103

Claims 154, 162-164, 167 and 247-249 are rejected as unpatentable over Wallace or Rhee or Wadstrom, in view of U.S. Patent No. 5,716,404 to Vacanti (hereafter "Vacanti").

The cited references do not teach or suggest the claimed features of claim 154, as amended. More specifically, none of Wallace, Rhee and Wadstrom teaches or suggests forming covalent bonds between a synthetic polymer having multiple activated groups and tissue in which the multiple activated groups (Y) of the synthetic polymer react with functional groups X of the tissue. Vacanti does not teach or suggest the features of amended claim 154 that are missing in Wallace, Rhee or Wadstrom. Vacanti's polymer is a matrix which supports cell proliferation for purpose of reconstructing breast tissue. There is no teaching or suggestion that the polymer in Vacanti has multiple activated groups that can react with functional groups of the tissue.

In addition, Vacanti does not teach or suggest the features of claims 162-164. Claims 162-164 are directed to adhesion prevention during breast surgery using a synthetic polymer having multiple activated groups. Vacanti, on the other hand, is limited to using a polymeric matrix as a scaffold to support cell proliferation for purpose of reconstructing breast tissue.

Finally, Vacanti does not teach or suggest the features of claims 247-249. Claims 247-249 specify that the drug is a cell cycle inhibitor (*e.g.*, paclitaxel), which inhibits cell proliferation. This feature could not have been taught or suggested in Vacanti. In fact, Vacanti teaches away from using cell cycle inhibitors because the polymeric matrix in Vacanti serves to promote cell proliferation and tissue regrowth.

Accordingly, Wallace or Rhee or Wadstrom, alone or in combination with Vacanti, do not render claims 154, 162-164, 167 and 247-249 obvious.

Claims 154, 167 and 247-249 are rejected as unpatentable over Wallace, Rhee, or Wadstrom in view of U.S. Patent No. 5,922,676 to Pasqualini (hereafter "Pasqualini") and U.S. Published Application No. 2002/0055666 to Hunter (hereafter "Hunter").

The cited references do not teach or suggest the claimed features of claim 154, as amended. More specifically, none of Wallace, Rhee and Wadstrom teaches or suggests forming covalent bonds between a synthetic polymer having multiple activated groups and tissue in which the multiple activated groups (Y) of the synthetic polymer react with functional groups X of the tissue. Neither Pasqualini nor Hunter teaches or suggests the features of amended claim 154 that are missing in Wallace, Rhee or Wadstrom.

Pasqualini is limited to methods of inhibiting angiogenesis and cytokine-mediated endothelial cell growth and migration using superfibronectin, *i.e.*, adhesive multiple fibronectin molecules. Pasqualini does not teach or suggest that superfibronectin has multiple activated groups that can form covalent bonds with tissue.

In addition, Pasqualini does not teach or suggest the features of claim 167. Claim 167 is directed to a method of affecting (*e.g.*, mitigating or preventing) adhesion formation caused by colon tumor resection surgery. Pasqualini's disclosure is limited to inhibiting tumor growth, not adhesion formation due to surgery. Accordingly, Wallace or Rhee or Wadstrom, alone or in combination with Pasqualini, do not render claims 154, 162-164, 167 and 247-249 obvious.

Similarly, Hunter describes combining radioactive therapy and cell-cycle inhibitors for treating diseases. Hunter does not teach or suggest forming covalent bonds between a synthetic polymer having multiple activated groups and tissue in which the multiple activated groups (Y) of the synthetic polymer react with functional groups X of the tissue.

Accordingly, Wallace or Rhee or Wadstrom, alone or in combination with Hunter, do not render claims 154, 162-164, 167 and 247-249 obvious.

In view of the above amendments and discussion, all of the claims in the application are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,
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